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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/034, 372	03/04/98	SAY	J 12008.200US01

QM12/1122

EXAMINER

NATNITHITHADHA, N

ART UNIT

PAPER NUMBER

3736

10

DATE MAILED:

11/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/034,372</b>	Applicant(s) <b>Say et al</b>
	Examiner <b>Navin Natnithithadha</b>	Group Art Unit <b>3736</b>

Responsive to communication(s) filed on Jul 26, 1999.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-127 is/are pending in the application.

Of the above, claim(s) 3, 59-64, 79, 80, 85-91, and 123-126 is/are withdrawn from consideration.

Claim(s) 35-38, 70, 71, 112-117, 122, and 127 is/are allowed.

Claim(s) 10-13, 20-23, 26-30, 54, 74-78, 81, 83, 92-94, 100, 101, 103-105, 107 is/are rejected.

Claim(s) 1, 2, 4-9, 14-19, 24, 25, 31-34, 39-53, 55-58, 65-69, 72, 73, 82, 84, 95 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 and 6

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### **Part III DETAILED ACTION**

1. Claims 1-127 are presented for examination.

#### *Response to Amendment*

2. Claims 1, 2, 10-15, 20-22, 33, 34, 36-38, 48, 54-58, 70, 74, 81, 97, and 122 are amended.
3. Claim 127 is added.
4. Claims 3, 59-64, 79, 80, 85-91, and 123-126 are canceled.

#### *Drawings*

5. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

#### *Specification*

6. The disclosure is objected to because of the following informalities:  
on page 10, line 19, PCT Patent Application Number is missing; and  
on page 16, line 22, U.S. Application Serial Number is missing.  
Appropriate correction is required when the information becomes available.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

*Claim Rejections - 35 USC § 102*

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 104, 105, 107, 108, and 118-120 are rejected under 35 U.S.C. 102(b) as being anticipated by Guilbeau et al, US 4,935,345.

Guilbeau et al teaches the invention (claims 104, 105, 107, and 108) as claimed, including an electrochemical sensor (e.g., see Abstract), comprising:

a substrate 10; and conductive material disposed on a surface of the substrate 10 to form a plurality of traces 12-20 (e.g., see col. 6, line 39 to col. 7, line 24 and see Fig. 1); wherein the plurality of conductive traces are separated on the surface of the substrate by 0.25 inches or less (e.g., see col. 7, line 50-66 and see col. 11, line 47-59).

Guilbeau et al teaches the invention (claim 118-120) as claimed, including method of determining a level of an analyte in a human (e.g., see Abstract), comprising:

generating a signal at thin film thermopile in response to the analyte; analyzing the signal to determine a level of the analyte; and producing a voltage between two conductive traces (e.g., see col. 4, line 29 to col. 5, line 19).

10. Claims 81 and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill et al. US 5,509,410.

Hill et al teaches the invention (claims 81 and 83) as claimed, including an electrochemical sensor for determining a level of an analyte in a fluid, comprising:

a substrate; a conductive material disposed on the substrate and forming a working electrode; and a catalyst disposed proximally to the working electrode to catalyze a reaction of the analyte resulting in a change in a level of a second compound; wherein the electrochemical sensor is responsive to the level of the second compound in the fluid (e.g., see col. 1, line 53 to col. 2, line 34).

*Claim Rejections - 35 USC § 103*

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 103, 10-13, 20, 21, 54, and 74-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al, US 5,509,410, in view of Guilbeau et al, US 4,935,345.

Hill et al teaches the invention (claim 103) substantially as claimed, including a sensor system, comprising:

a substrate; a conductive material disposed on the substrate to form a working electrode, the conductive material comprising carbon; and an enzyme disposed proximate to the working electrode (e.g., see col. 2, lines 26-35, and see col. 12, lines 33-46).

Hill et al does not teach a subcutaneous implantable sensor. He teaches using drop of blood placed onto the sensing electrode (e.g., see col. 2, lines 26-34). However, Guilbeau et al teaches a implantable biochemical sensor comprising a substrate, a conductive material, and an enzyme (e.g., see Abstract, see Fig. 5, and see col. 12, line 60 to col. 13, line 15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Hill et al with the teachings of Guilbeau et al to accurately measure, within the body of a human, the concentration of particular chemicals within body fluids.

As to claims 10 and 11, Hill et al teaches the electrochemical sensor configured for in vitro operation (e.g., see col. 2, lines 26-34) and Guilbeau et al teaches the electrochemical sensor for in vivo operation (e.g., see Abstract).

As to claims 12 and 13, Guilbeau et al teaches a substrate made of glass, silicon, ceramic, or plastic (e.g., see col. 2, lines 26-38) and Hill et al teaches a substrate made of epoxy glass (e.g., see col. 8, lines 12-24).

As to claim 20, Guilbeau et al teaches the conductive material comprises of metal (e.g., see col. 6, lines 26-57).

As to claim 21, Hill et al teaches the conductive material comprises carbon (e.g., see col. 12, lines 33-46).

As to claim 54, Guilbeau teach the analyte as glucose (e.g., see Abstract).

As to claim 74, both Hill et al and Guilbeau et al teaches a method of determining a level of an analyte in a fluid, the method comprising: contacting the fluid with the electrochemical sensor; generating an electrical signal in the sensor in response to the presence of the analyte; and determining a level of the analyte from the electrical signal (e.g., see Abstracts).

As to claim 75-78, Hill et al teaches the electrochemical sensor configured for in vitro operation (e.g., see col. 2, lines 26-34) and Guilbeau et al teaches the electrochemical sensor for in vivo operation (e.g., see Abstract).

13. Claims 92-94, 22, 23, 26-30, 100, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al, US 5,509,410.

Hill et al teaches the invention (claim 92) as claimed, including an electrochemical sensor, comprising:

a substrate; and a working electrode disposed on the substrate, the working electrode comprising a carbon material (e.g., see col. 4, lines 16-40).

As to claim 92-94, Hill et al does not disclose the width of the working electrode. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Hill et al because it is a matter of engineering choice based on design parameters.

As to claims 22, 23, 26-30, Hill et al teaches using an active electrode, positioned to contact the liquid mixture and the first conductor, comprises a deposit of an enzyme capable of catalyzing a reaction (e.g., see col. 1, line 53 to col. 2, line 14). The enzyme is glucose oxidase or glucose dehydrogenase.

As to claims 100 and 101, Hill et al teaches the active electrode formed by printing an ink comprising a conductive compound (e.g., see col. 2, lines 1-14).

14. Claims 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guilbeau et al, US 4,935,345, in view of Hill et al, US 5,509,410.

Guilbeau et al teaches the invention (claim 109) as claimed including an electrochemical sensor, comprising:

a substrate 10, conductive material disposed on the substrate to form a working electrode 12; and a contact pad 13 disposed on the substrate 10 and connected to the working electrode 12 (e.g., see Figs. 1A-1D).

Guilbeau et al does not teach the contact pad made of non-metallic conductive material. However, Hill et al teaches a electrochemical sensor using an electrode made of a conductive

material such as carbon (e.g., see col. 4, lines 30-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Hill et al with the teachings of Guilbeau et al to accurately measure, within the body of a human, the concentration of particular chemicals within body fluids.

*Allowable Subject Matter*

15. Claims 35-38, 70, 71, 112-117, 122, and 127 are allowed.
16. Claims 1, 2, 4-9, 14-19, 24, 25, 31-34, 39-53, 55-58, 65-69, 72, 73, 82, 84, 95-99, 102, 106, 110, 111, and 121 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,820,551 and US 5,727,548 are related U.S. Patents to US 5,509,410 which was used in the rejections above.

US 5,954,685 teaches an electrode assembly for use in a transdermal analyte sensor.

US 5,71,861 teaches a electrochemical sensor system for measuring analyte concentrations in a sample fluid.

US 5,400,782 teaches an electrode for monitoring and diagnostic applications which includes a fusible conductive substrate to which are fused the other components, such as the conductor, of the electrode.

US 5,322,063 teaches a biosensor for amperometric measurements wherein the measuring electrode is made of an electrically conductive carrier made of carbon.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emr. Navin Natnithithadha, whose telephone number is (703) 305-2445. The examiner can normally be reached on M-TH from 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by phone fail, the examiner's supervisor, Cary E. O'Connor, can be reached at (703) 308-2701. Additionally, the fax phone for Art Unit 3736 is (703) 308-0758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-1148.

Navin Natnithithadha  
Patent Examiner  
Art Unit 3736  
November 9, 1999

  
CARY O'CONNOR  
SUPERVISORY PATENT EXAMINER  
GROUP 3700